

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

FOREST LABORATORIES, INC.,)	
FOREST LABORATORIES HOLDINGS,)	
LTD., MERZ PHARMA GMBH & CO.)	
KGAA, and MERZ PHARMACEUTICALS)	
GMBH,)	
Plaintiffs,)
v.)
COBALT LABORATORIES INC., LUPIN)	
PHARMACEUTICALS, INC., LUPIN LTD.,)	
ORCHID PHARMACEUTICALS INC.,)	
ORCHID CHEMICALS &)	
PHARMACEUTICALS LTD. (d/b/a ORCHID)	
HEALTHCARE), TEVA)	
PHARMACEUTICALS USA, INC.,)	
UPSHER-SMITH LABORATORIES, INC.,)	
WOCKHARDT USA INC., and)	
WOCKHARDT LIMITED,)	
Defendants.)

C.A. No. _____

COMPLAINT

Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively "Plaintiffs") for their Complaint against Defendants Cobalt Laboratories Inc., Lupin Pharmaceuticals, Inc., Lupin Ltd., Orchid Pharmaceuticals Inc., Orchid Chemicals & Pharmaceuticals Ltd. (d/b/a Orchid Healthcare), Teva Pharmaceuticals USA, Inc., Upsher-Smith Laboratories, Inc., Wockhardt USA Inc., and Wockhardt Limited (collectively "Defendants") hereby allege as follows:

PARTIES

1. Plaintiff Forest Laboratories, Inc. ("Forest Labs") is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

2. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda (referred to herein, together with Forest Laboratories, Inc., as "Forest").

3. Plaintiff Merz Pharma GmbH & Co. KGaA is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany.

4. Plaintiff Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany (referred to herein, together with Merz Pharma GmbH & Co. KGaA, as "Merz").

5. Upon information and belief, Defendant Cobalt Laboratories Inc. ("Cobalt") is a Delaware corporation having a principal place of business at 24840 Tamiami Trail, Bonita Springs, Florida 34134.

6. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a Virginia corporation, and the wholly-owned subsidiary and agent of Defendant Lupin Ltd., having a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, Defendant Lupin Pharma manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

7. Upon information and belief, Defendant Lupin Ltd. ("Lupin") is an Indian corporation having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Upon information and belief, Defendant Lupin, itself and through its wholly-owned subsidiary and agent Defendant Lupin Pharma, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

8. Upon information and belief, Defendant Orchid Pharmaceuticals Inc. ("Orchid Pharma") is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Orchid Chemicals & Pharmaceuticals Ltd., having a principal place of business at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

9. Upon information and belief, Defendant Orchid Chemicals & Pharmaceuticals Ltd. (d/b/a Orchid Healthcare) ("Orchid") is an Indian corporation having a place of business at Orchid Towers, 313 Valluvar Kottam High Road, Nungambakkam, Chennai, Tamil Nadu 600 034 India and a place of business at Plat No. B3-B6 & B11-B14, Sipcot Industrial Park, Irungattukottai, Sriperumbudur (TK) - 602 105, Kancheepuram District, Tamil Nadu, India. Upon information and belief, Defendant Orchid, itself and through its wholly-owned subsidiary and agent Defendant Orchid Pharma, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

10. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation having a principal place of business at 1090 Horsham Rd., PO Box 1090, North Wales, Pennsylvania 19454.

11. Upon information and belief, Defendant Upsher-Smith Laboratories, Inc. ("Upsher-Smith") is a Minnesota corporation having a principal place of business at 6701

Evenstad Drive, Maple Grove, Minnesota 55369. Upon information and belief, Defendant Upsher-Smith manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

12. Upon information and belief, Defendant Wockhardt USA Inc. ("Wockhardt USA") is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Wockhardt, having a principal place of business at 75 Ronald Reagan Boulevard, Warwick, NY 10990.

13. Upon information and belief, Defendant Wockhardt Limited ("Wockhardt") is an Indian corporation having a principal place of business at Wockhardt Tower, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Upon information and belief, Defendant Wockhardt, itself and through its wholly-owned subsidiary and agent Defendant Wockhardt USA, manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

14. This is a civil action for infringement of United States Patent No. 5,061,703 ("the '703 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

16. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to

foreseeable harm and injury to Plaintiffs, including Plaintiff Forest Labs, a Delaware corporation. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

17. This Court has personal jurisdiction over Defendant Cobalt by virtue of the fact that, *inter alia*, Cobalt is a Delaware corporation.

18. This Court has personal jurisdiction over Defendant Lupin Pharma by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

19. This Court has personal jurisdiction over Defendant Lupin by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its subsidiary and agent Lupin Pharma.

20. This Court has personal jurisdiction over Defendant Orchid Pharma by virtue of the fact that, *inter alia*, Orchid Pharma is a Delaware corporation.

21. This Court has personal jurisdiction over Defendant Orchid by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Orchid Pharma; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Orchid Pharma.

22. This Court has personal jurisdiction over Defendant Teva by virtue of the fact that, *inter alia*, Teva is a Delaware corporation.

23. This Court has personal jurisdiction over Defendant Upsher-Smith by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

24. This Court has personal jurisdiction over Defendant Wockhardt USA by virtue of the fact that, *inter alia*, Wockhardt USA is a Delaware corporation.

25. This Court has personal jurisdiction over Defendant Wockhardt by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Wockhardt USA; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Wockhardt USA.

26. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1331 and 1400(b).

THE PATENT-IN-SUIT

27. On October 29, 1991, the '703 patent, titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Merz has been, and continues to be, the sole assignee of the '703 patent since its issuance.

28. Forest is the exclusive licensee of the '703 patent in the United States. Forest holds New Drug Application ("NDA") No. 21-487 for Namenda® brand memantine hydrochloride tablets. The '703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Namenda®.

29. Forest is the exclusive distributor of Namenda® in the United States.

30. On August 18, 2004, Merz submitted a request to the PTO for reexamination of the '703 patent. The PTO issued a reexamination certificate (Exhibit B) for the '703 patent on November 7, 2006.

ACTS GIVING RISE TO THIS ACTION

Count I – Infringement Of The '703 Patent By Defendant Cobalt

31. Upon information and belief, Defendant Cobalt submitted ANDA No. 90-042 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.

§ 355(j)). Cobalt's ANDA No. 90-042 seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Cobalt Generic Products"). Cobalt's ANDA No. 90-042 specifically seeks FDA approval to market the Cobalt Generic Products prior to the expiration of the '703 patent.

32. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Cobalt alleged in ANDA No. 90-042 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Cobalt Generic Products. Plaintiffs received written notification of ANDA No. 90-042 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 6, 2007.

33. Cobalt's submission of ANDA No. 90-042 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Cobalt commercially manufactures, uses, offers to sell, sells, or imports any of the Cobalt Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

34. Cobalt was aware of the '703 patent prior to filing ANDA No. 90-042.

35. Cobalt's actions render this an exceptional case under 35 U.S.C. § 285.

36. Plaintiffs will be irreparably harmed by Cobalt's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count II – Infringement Of The '703 Patent By Defendants Lupin And Lupin Pharma

37. Upon information and belief, Defendant Lupin, through its subsidiary and agent Lupin Pharma, submitted ANDA No. 90-051 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the

commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride (“the Lupin Generic Products”). ANDA No. 90-051 specifically seeks FDA approval to market the Lupin Generic Products prior to the expiration of the ‘703 patent.

38. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Lupin alleged in ANDA No. 90-051 that the claims of the ‘703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Lupin Generic Products. Plaintiffs received written notification of ANDA No. 90-051 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 14, 2007.

39. Lupin’s submission of ANDA No. 90-051 to the FDA, through its subsidiary and agent Lupin Pharma, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the ‘703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin commercially manufacturers, uses, offers to sell, sells, or imports any of the Lupin Generic Products, or induces or contributes to any such conduct, it would further infringe the ‘703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

40. Lupin Pharma is jointly and severally liable for any infringement of the ‘703 patent. Upon information and belief, Lupin Pharma participated in, contributed to, aided, abetted and/or induced Lupin’s submission of ANDA No. 90-051 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

41. Lupin Pharma’s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-051 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the ‘703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Pharma commercially manufactures, uses, offers to sell, sells, or imports any of the

Lupin Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

42. Lupin and Lupin Pharma were aware of the '703 patent prior to filing ANDA No. 90-051.

43. Lupin's and Lupin Pharma's actions render this an exceptional case under 35 U.S.C. § 285.

44. Plaintiffs will be irreparably harmed by Lupin's and Lupin Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count III – Infringement Of The '703 Patent By Defendants Orchid And Orchid Pharma

45. Upon information and belief, Defendant Orchid, through its subsidiary and agent Orchid Pharma, submitted ANDA No. 90-044 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Orchid Generic Products"). ANDA No. 90-044 specifically seeks FDA approval to market the Orchid Generic Products prior to the expiration of the '703 patent.

46. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Orchid alleged in ANDA No. 90-044 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Orchid Generic Products. Plaintiffs received written notification of ANDA No. 90-044 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 11, 2007.

47. Orchid's submission of ANDA No. 90-044 to the FDA, through its subsidiary and agent Orchid Pharma, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Orchid commercially manufactures, uses, offers to sell, sells, or imports any of the Orchid Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

48. Orchid Pharma is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Orchid Pharma participated in, contributed to, aided, abetted and/or induced Orchid's submission of ANDA No. 90-044 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

49. Orchid Pharma's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-044 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Orchid Pharma commercially manufactures, uses, offers to sell, sells, or imports any of the Orchid Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

50. Orchid and Orchid Pharma were aware of the '703 patent prior to filing ANDA No. 90-044.

51. Orchid's and Orchid Pharma's actions render this an exceptional case under 35 U.S.C. § 285.

52. Plaintiffs will be irreparably harmed by Orchid's and Orchid Pharma's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count IV – Infringement Of The ‘703 Patent By Defendant Teva

53. Upon information and belief, Defendant Teva submitted ANDA No. 90-052 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Teva’s ANDA No. 90-052 seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride (“the Teva Generic Products”). Teva’s ANDA No. 90-052 specifically seeks FDA approval to market the Teva Generic Products prior to the expiration of the ‘703 patent.

54. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Teva alleged in ANDA No. 90-052 that the claims of the ‘703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Teva Generic Products. Plaintiffs received written notification of ANDA No. 90-052 and its § 505(j)(2)(A)(vii)(IV) allegation on or about November 30, 2007.

55. Teva’s submission of ANDA No. 90-052 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the ‘703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Teva commercially manufactures, uses, offers to sell, sells, or imports any of the Teva Generic Products, or induces or contributes to any such conduct, it would further infringe the ‘703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

56. Teva was aware of the ‘703 patent prior to filing ANDA No. 90-052.

57. Teva’s actions render this an exceptional case under 35 U.S.C. § 285.

58. Plaintiffs will be irreparably harmed by Teva’s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count V – Infringement Of The ‘703 Patent By Defendant Upsher-Smith

59. Upon information and belief, Defendant Upsher-Smith submitted ANDA No. 90-043 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Upsher-Smith’s ANDA No. 90-043 seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams, 10 milligrams, 15 milligrams, and 20 milligrams of memantine hydrochloride (“the Upsher-Smith Generic Products”). Upsher-Smith’s ANDA No. 90-043 specifically seeks FDA approval to market the Upsher-Smith Generic Products prior to the expiration of the ‘703 patent.

60. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Upsher-Smith alleged in ANDA No. 90-043 that the claims of the ‘703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Upsher-Smith Generic Products. Plaintiffs received written notification of ANDA No. 90-043 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 14, 2007.

61. Upsher-Smith’s submission of ANDA No. 90-043 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the ‘703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Upsher-Smith commercially manufactures, uses, offers to sell, sells, or imports any of the Upsher-Smith Generic Products, or induces or contributes to any such conduct, it would further infringe the ‘703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

62. Upsher-Smith was aware of the ‘703 patent prior to filing ANDA No. 90-043.

63. Upsher-Smith’s actions render this an exceptional case under 35 U.S.C. § 285.

64. Plaintiffs will be irreparably harmed by Upsher-Smith's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count VI – Infringement Of The ‘703 Patent By Defendants Wockhardt And Wockhardt USA

65. Upon information and belief, Defendant Wockhardt, through its subsidiary and agent Wockhardt USA, submitted ANDA No. 90-073 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale of generic tablet products containing 5 milligrams and 10 milligrams of memantine hydrochloride ("the Wockhardt Generic Products"). ANDA No. 90-073 specifically seeks FDA approval to market the Wockhardt Generic Products prior to the expiration of the ‘703 patent.

66. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Wockhardt alleged in ANDA No. 90-073 that the claims of the ‘703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Wockhardt Generic Products. Plaintiffs received written notification of ANDA No. 90-073 and its § 505(j)(2)(A)(vii)(IV) allegation on or about December 15, 2007.

67. Wockhardt's submission of ANDA No. 90-073 to the FDA, through its subsidiary and agent Wockhardt USA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the ‘703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Wockhardt commercially manufactures, uses, offers to sell, sells, or imports any of the Wockhardt Generic Products, or induces or contributes to any such conduct, it would further infringe the ‘703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

68. Wockhardt USA is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Wockhardt USA participated in, contributed to, aided, abetted and/or induced Wockhardt's submission of ANDA No. 90-073 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

69. Wockhardt USA's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-073 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Wockhardt USA commercially manufactures, uses, offers to sell, sells, or imports any of the Wockhardt Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b) and/or (c).

70. Wockhardt and Wockhardt USA were aware of the '703 patent prior to filing ANDA No. 90-073.

71. Wockhardt's and Wockhardt USA's actions render this an exceptional case under 35 U.S.C. § 285.

72. Plaintiffs will be irreparably harmed by Wockhardt's and Wockhardt USA's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. That all Defendants have infringed the '703 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' respective ANDAs identified in this Complaint shall not be earlier than the expiration date of the '703 patent, including any extensions;

C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing any of the proposed generic versions of Plaintiffs' Namenda® brand product identified in this Complaint and any other product that infringes or induces or contributes to the infringement of the '703 patent, prior to the expiration of the '703 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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